

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 53D0662176	<b>(X3) Date Survey Completed</b> 09/28/2022
<b>Name of Provider or Supplier</b> Memorial Hospital Of Carbon County	<b>Street Address, City, State</b> 2221 W Elm St, Rawlins, WY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records, review of the CMS (Center for Medicare and Medicaid Services) 209 Laboratory Personnel Report, and staff interview, the laboratory failed to include the respiratory therapists in the rotation of personnel performing blood gas (pH, partial pressure of oxygen, partial pressure of carbon dioxide) testing for 3 of 3 proficiency testing events reviewed from September 2021 through September 2022. The laboratory performed approximately 365 patient blood gases per year. The findings were: 1. Review of the CMS 209 Laboratory Personnel Report dated 9/19/22 showed 4 respiratory therapists were listed as testing personnel performing moderate complexity testing. 2. Review of the 3 American Proficiency Institute Chemistry Core Proficiency testing events from September 2021 through September 2022 showed the blood gas section of the events was performed by laboratory personnel which did not include the respiratory therapists. 3. Interview with the technical supervisor and the respiratory therapist supervisor on 9/27/22 at 3:47 PM revealed blood gas testing was shared between the respiratory therapists and the laboratory staff using the Abbott iSTAT analyzer. 4. Interview with the laboratory director on 9/27/22 at 3:56 PM confirmed the respiratory therapists had not participated in the proficiency testing events.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of personnel files, review of the CMS (Center for Medicare and Medicaid Services) 209 Laboratory Personnel Report, lack of documentation, review of policy and procedure, and staff interview, the technical supervisor failed to complete competency assessment for 4 of 4 respiratory therapists (RT #1, RT #2, RT #3, RT #4) as required for 2 of 2 years reviewed (2021, 2022). The findings were: 1. Review of the laboratory's personnel files showed the following concerns: a. Review of the personnel file for RT #1 showed an initial competency assessment was completed in March 2021 and a 6-month competency assessment in October 2021. There was no evidence an annual competency assessment had been completed. b. Review of the personnel file for RT #2 showed the RT had been trained on the Abbott iSTAT analyzer in July 2020 and a 6-month competency assessment had been completed in October 2021. There was no evidence an annual competency assessment had been completed. c. Review of the personnel file for RT #3 showed an initial competency assessment had been completed on 1/4/22. There was no evidence a 6-month competency assessment had been completed. d. Review of the personnel file for RT #4 showed an initial competency assessment had been completed in March 2021 and a 6-month competency assessment had been completed in December 2021. There was no evidence an annual competency assessment had been completed. 2. Interview with the technical supervisor on 9/27/22 at 3:15 PM revealed the respiratory therapists had started performing blood gas patient testing in May of 2021 using the Abbott iSTAT instrument. In addition, the technical supervisor confirmed the competency assessments had not been completed as required. 3. Review of the Personnel Competency and Records policy showed "...For nonwaived testing: During the first year of an individual's duties, competency must be assessed at least semiannually. After an individual has performed his/her duties for one year, competency must be assessed at least annually..."

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test menu, lack of documentation, and staff interview, the laboratory failed to at least twice annually verify the accuracy of the C-reactive protein (CRP) analyte for 13 months of testing reviewed. The laboratory performed approximately 534 CRP patient tests annually. The findings were: 1. Review of the laboratory's test menu showed the laboratory performed CRP testing. 2. Review of the laboratory's records showed no evidence the analyte of CRP had been verified for accuracy at least twice annually. 3. Interview with the laboratory director on 9/27/22 at 2:21 PM confirmed the laboratory had not verified the accuracy of the CRP analyte as required.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of calibration verification records, lack of documentation and staff interview, the laboratory failed to verify the reportable range at least every 6 months using testing materials with values at the zero or minimal level, the mid-level, and the upper-level of the reportable range for Troponin I, enzymatic carbon dioxide (CO<sub>2</sub>), alcohol, ammonia, iron, uric acid, urine total protein, urine creatinine, free thyroxine (FT<sub>4</sub>), vitamin B-12, total bilirubin, direct bilirubin, prostatic-specific antigen (PSA), creatinine kinase-MB (CKMB), hemoglobin A<sub>1C</sub>, beta-human chorionic gonadotropin (BhCG), alkaline phosphatase (ALP), alanine aminotransferase (ALT), amylase, aspartate aminotransferase (AST), creatinine kinase (CK), and lipase on the Roche Cobas 6000. In addition, the laboratory failed to verify the reportable range for blood gases (pH, partial pressure of oxygen, partial pressure of carbon dioxide) analyzed on the Abbott iSTAT instrument for 2 of 2 years of testing (2021, 2022). The laboratory performed approximately 32,787 tests on the Roche Cobas analyzer and 365 blood gases on the Abbott iSTAT analyzer annually. The findings were: 1. Review of the laboratory's records showed a calibration verification study had not been completed on the Abbott iSTAT instrument for the analytes of pH, partial pressure of oxygen, partial pressure of carbon dioxide) since the implementation of the instrument in May 2021. 2. Review of the laboratory's records showed the following concerns related to the Roche 6000 analyzer: a. CO<sub>2</sub>, alcohol, ammonia, iron, uric acid, urine total protein, urine creatinine, total bilirubin and direct bilirubin was missing the 2021 calibration verification studies. b. The last completed calibration verification studies for Troponin I, BhCG, and Vitamin B-12 were completed in November 2021. c. A calibration verification study was completed for FT<sub>4</sub> and CKMB in January 2021 and January 2022. d. The last completed calibration verification study for PSA was completed on 1/13/22. e. The last completed calibration verification study for hemoglobin A<sub>1C</sub> was completed on 12/3/21. f. The last completed calibration verification study for ALP, ALT, amylase, AST, CK and lipase was completed on 12/3/21. 3. Interview with the technical supervisor (TS) on 9/28/22 at 10:21 AM revealed the laboratory did not have a system in place to ensure the calibration verification studies were completed as required. In addition, the TS confirmed calibration verification studies on the Abbott iSTAT instrument had not

been completed.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of patient testing records, review of quality control (QC) records, lack of documentation, review of the laboratory's individualized quality control plan (IQCP), and staff interview, the laboratory failed to perform two levels of control once a month, with a new shipment, or with a new lot number for 3 of 5 months of testing reviewed (May 2022 through July 2022) for patient blood gas (pH, partial pressure of carbon dioxide, partial pressure of oxygen) testing using the Abbott iSTAT instrument. This failure affected 9 patient samples (#3437475, #3440101, #3437077, #3436401, #3436678, #3436549, #3435724, #3436390, #3435537). The findings were: 1. Review of patient testing records showed the following concerns: a. Blood gases were performed on patient #3437077 on 5/27/22; #3436401 on 5/15/22; #3436678 on 5/20/22; #3436549 on 5/19/22; #3436390 on 5/14/22 at 3:11 PM and at 4:54 PM; #3440101 on 7/27/22 and 7/28/22; using reagent lot number 23D213390243. Review of the QC records showed QC was performed on 5/6/22; however, the analyte of partial pressure of carbon dioxide (pCO<sub>2</sub>) on the level 1 control was outside of the acceptable QC range. There was no evidence the failure of pCO<sub>2</sub> was investigated. b. Blood gases were performed on patient #3435537 on 5/1/22; #3435724 on 5/4/22; and #3437475 on 6/5/22 using reagent lot number 230212920243. Review of the QC records showed QC had not been performed on the lot number until 6/7/22. 2. Review of the IQCP, last reviewed on 8/10/22, showed external QC must be performed with each new lot number or shipment or every 30 days. 3. Review of a QC variance form dated 7/18/22 showed the failure of the pCO<sub>2</sub> analyte on 5/6/22 had been noted; however no corrective action was taken and reagent lot number 230D213390243 continued to be used for patient testing until 7/28/22. 4. Interview with the technical supervisor on 9/27/22 at 5:30 PM revealed the laboratory was responsible for performing quality control on the Abbott iSTAT instrument and confirmed no further documentation was available.

**D5547**

**HEMATOLOGY**  
CFR(s): 493.1269(c)(d)

(c) For manual coagulation tests-- (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on observation, review of coagulation records, and staff interview, the laboratory failed to ensure the normal patient prothrombin time mean (geomean) for a new lot number of Neoplastin had been entered into the Diagnostica Stago Compact Max coagulation analyzer prior to analyzing patient samples with the new lot of reagent. The laboratory performed 650 patient prothrombin time tests since the reagent lot change occurred on 2/1/22. The findings were: 1. Observation of the Diagnostica Stago Compact Max coagulation analyzer on 9/28/22 at 11 AM showed Neoplastin lot number 259495 was in use with an International Sensitivity Index of 1.28 and a geomean of 12.9 seconds. 2. Review of the coagulation records showed the laboratory had established a geomean of 13.547 seconds on 1/27/22 for Neoplastin lot number 259495. 3. Interview with the technical consultant on 9/28/22 at 11:26 AM confirmed the correct geomean had not been entered into the Diagnostica Stago Compact Max coagulation analyzer.